DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 30 2002

3580 '02 FEB -1 A9:20

Robert W. Pollock
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

Re: Docket No. 01P-0356/CP1

Dear Mr. Pollock:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on August 15, 2001. Your petition requests that the Commissioner of Food and Drugs amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) to designate Cortef tablets (hydrocortisone) 5 milligrams (mg), 10 mg, and 20 mg (NDA 08-697), a Pharmacia and Upjohn product, as a designated reference listed drug product for hydrocortisone tablets. Currently, Hydrocortone tablets (hydrocortisone) (NDA 08-506), a Merck product, is the reference listed drug product.

This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0356

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